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# Magnetic Guidance System for Cardiac Electrophysiology

## A Prospective Trial of Safety and Efficacy in Humans

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**OBJECTIVES** We evaluated in humans the safety and efficacy of a novel magnetic guidance system (MGS) for electrophysiological mapping, pacing, and ablation.

**BACKGROUND** Catheter ablation of atrial fibrillation and other complex arrhythmias requires precise catheter manipulation and stabilization. We have shown in animals that the MGS can precisely manipulate a mapping catheter within the heart with an external magnetic field rather than manual catheter control.

**METHODS** Thirty-one adults referred for diagnostic electrophysiology studies were enrolled in a prospective trial of the MGS. The magnetic catheter was navigated to preselected sites in the right atrium (RA) and right ventricle (RV) in the first 20 patients. Electrograms were recorded at each target site, and pacing thresholds were measured. In a subset of five patients, RA and RV electrograms and stimulation thresholds were recorded with both a standard ablation catheter and the magnetic catheter. Eleven additional patients were recruited for supraventricular tachycardia (SVT) mapping, and seven of these underwent ablation.

**RESULTS** Navigation was successful in 200 of 202 predetermined right-sided navigation targets and 13 of 13 targets in the left atria. Pacing thresholds and electrogram amplitudes in the RA and RV were not significantly different between the standard and magnetic catheters. The SVT mapping with the magnetic catheter was successful in 13 patients, including 4 with left-sided accessory pathways. The MGS was used for successful ablation of SVT in seven of seven patients. There were no procedural complications.

**CONCLUSIONS** These results demonstrate that the MGS can be used for intracardiac mapping, pacing, and ablation safely and effectively. (J Am Coll Cardiol 2003;42:1952–8) © 2003 by the American College of Cardiology Foundation

Catheter ablation of complex arrhythmias requires precise manipulation and stability of the ablation catheter for success. Challenges characteristic of difficult ablation procedures include long procedure times, extended fluoroscopic exposure to the patient and physician, and a greater risk of arrhythmia recurrence. Limitations of conventional manually deflected ablation catheters may contribute to these challenges. Magnetic force has been used for intravascular catheter manipulation beginning with the work of Tillander (1), who restricted his study to manipulation of a catheter to major branches of the aorta. Ram and Meyer (2) demonstrated the first use of this methodology in humans. These initial efforts were limited by the low field strength and large size of available electromagnets as well as a lack of precise, three-dimensional control of the magnetic field vector. Subsequent developments have incorporated stereotactic localization and computer-controlled vectors for improved guidance (3). A magnetically guided ablation catheter promises to address the constraints of conventional ablation catheters that depend on mechanical deflection mechanisms.

We have participated in the development of a novel magnetic guidance system (MGS) for intracardiac electrophysiological procedures (4). In animals, we have demonstrated that magnetic catheter navigation is precise and compatible with intracardiac pacing, electrogram recording, and endocardial radiofrequency ablation. The endocardial force exerted by the magnetic catheter is comparable to that exerted by a standard deflectable catheter, and the risk of endocardial injury appears to be minimal.

This is the first prospective human trial of the MGS. The study objectives were to demonstrate the equivalence of the magnetic catheter performance to a standard 4-mm-tip ablation catheter and to document the safety and efficacy of the MGS for intracardiac recording, mapping, pacing, and radiofrequency ablation.

## METHODS

**MGS.** The trial was performed with the MGS (Stereotaxis, Inc., St. Louis, Missouri), which manipulates a specially designed electrophysiology catheter with an external magnetic field. The 7F magnetic catheter contains a

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**Abbreviations and Acronyms**

AV = atrioventricular
ECG = electrocardiogram
LAO = left anterior oblique
MGS = magnetic guidance system
RA = right atrium
RAO = right anterior oblique
RV = right ventricle/ventricular
SVT = supraventricular tachycardia

small permanent magnet in the tip that interacts with the prevailing magnetic field. The magnetic field exerts a force on the permanent magnet located in the catheter tip (4). The magnitude of the force exerted on the catheter is maximal when the catheter is perpendicular to the magnetic field and goes to zero when the catheter aligns parallel to the magnetic field. Animal studies have demonstrated that the 0.15T field strength utilized by the MGS exerts a force on the catheter comparable to that achieved with a standard manual deflection mechanism. The magnetic catheter and the MGS are shown in Figure 1. The MGS consists of a housing containing three orthogonal electromagnets cooled by liquid helium, biplanar digital fluoroscopic imaging plates that are unaffected by the magnetic field, and a conventional fluoroscopy table. Directional catheter navigation is performed with a graphical user interface (Fig. 2A). A desired magnetic field vector is drawn on a digitization tablet and displayed on orthogonal fluoroscopic views, as shown in Figure 2B. A control computer then calculates the appropriate currents to each of the superconducting electromagnets to produce the chosen composite magnetic field vector. The resolution of the MGS is <1°. Typical manipulations of the magnetic field vector require from 5 to 20 s for the MGS to redirect the field vector in a new direction, with time proportional to the magnitude of the directional change.

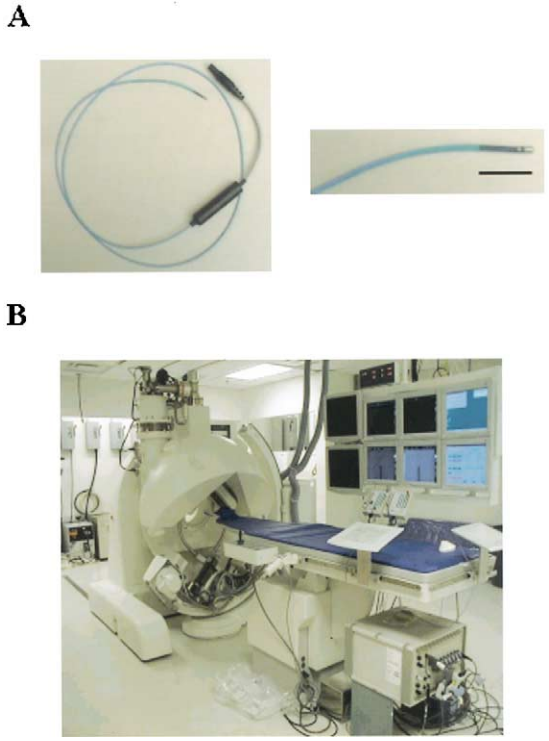


**Figure 1.** Magnetic catheter and magnetic guidance system (MGS) **(A)** Photographs of the 7F magnetic catheter. A closeup of the catheter tip is shown on the **right**. A permanent magnet embedded within the tip of the catheter interacts with a prevailing magnetic field. A standard, platinum 4-mm-tip electrode and a proximal ring electrode are used for endocardial recording and pacing. The **scale bar** is 20 mm. **(B)** A photograph of the MGS. This system consists of a housing that surrounds the patient's torso; the system also contains an electromagnetic array, a digital biplanar fluoroscope, a standard fluoroscopy table, and a graphical workstation for catheter navigation. The system is shown with the fluoroscopy table withdrawn from the electromagnet housing.

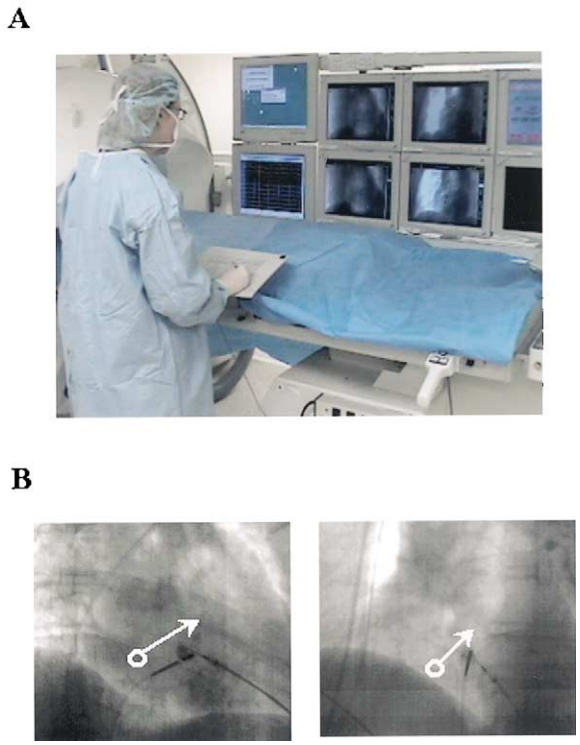


**Figure 2.** Magnetic navigation. **(A)** Photograph of catheter navigation with the magnetic guidence system. The catheter is guided by drawing a magnetic field vector on a graphical digitization tablet at the side of the fluoroscopy table as shown. The magnetic field vector is drawn and displayed overlying two orthogonal fluoroscopic views to specify a unique three-dimensional magnetic field vector. The magnetic field is then activated through the digitization tablet, and the catheter aligns parallel with the selected magnetic field vector. **(B)** Orthogonal fluoroscopic views used to specify the magnetic field vector. The images displayed (left anterior oblique **[left]**, right anterior oblique **[right]**) show the magnetic catheter aligning parallel to the chosen magnetic field vector to reach the His bundle recording site in a patient.

**Trial design.** The objectives of the trial design were to test the safety and efficacy of the MGS for intracardiac navigation, recording, and pacing. The primary end point for the trial was successful navigation and recording at preselected intracardiac targets within the right atrium (RA) and right ventricle (RV). The secondary end point for the trial was the measurement of stimulation thresholds with the magnetic catheter within the RA and RV. The efficacy of the MGS

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was assessed by the achievement of the end points of the study. The sample size of 200 intracardiac navigation targets, 10 sites in each of 20 patients, was chosen to determine the navigation success rate within 4%. Navigation success at a particular site was judged fluoroscopically and electrophysiologically. Catheter performance was also assessed by measurement of stimulation thresholds at two sites, the RA and RV, in each patient. Successful stimulation was defined as a threshold of <4 mA. With this sample size (40 sites), the study had 80% power to detect a difference between a successful stimulation rate of 98% and a successful stimulation rate of 100%.

After 20 patients were recruited, the trial was expanded to include navigation to left atrial and left ventricular sites as well as ablation of supraventricular tachycardia (SVT). The catheter used for patients undergoing ablation has been modified from the original to include a thermocouple for temperature control. This trial expansion is ongoing, but data from the first seven patients are included in this publication for SVT ablation and navigation to left-sided targets.

Prior work in experimental animals (4) investigated the risk of cardiac perforation with the MGS by attempting to navigate outside the cardiac silhouette. This catheter manipulation did not cause any histological damage to the endocardial surface. The safety of the MGS was assessed in the present trial in two ways. First, a complete echocardiographic evaluation with Doppler studies was performed immediately before and after catheter navigation with the MGS. In addition, patients had a telephone interview performed 7 to 10 days later to assess their recovery from the procedure. The safety of the MGS was prospectively stated as an absence of serious complications of the procedure defined as structural heart damage visible by echocardiography, pericardial effusion, hypotension, or death.

Electrogram comparisons were made by an electrophysiologist blinded to the identity of the catheter associated with a particular recording. The electrograms were judged as either acceptable or unacceptable.

**Inclusion criteria.** The trial was conducted with the approval and oversight of the Washington University Human Studies Committee. Patients able to give informed consent who were referred to the clinical cardiac electrophysiology service for diagnostic electrophysiology testing were recruited for the trial. Only patients older than 18 years were considered for recruitment. Patient characteristics are given in Table 1.

**Exclusion criteria.** Patients were excluded if they could not be safely exposed to a magnetic field owing to implanted devices such as a cardioverter-defibrillator, pacemaker, or vascular clips. Other exclusion criteria included left bundle branch block, body weight >300 pounds, claustrophobia, hemodynamic instability, recent myocardial infarction, recent cardiac surgery, or ongoing participation in experimental protocols.

**Table 1.** Patient Characteristics

| | |
|---|---|
| M (n)/F (n) | 18/13 |
| Age average, yrs (range) | 52 (20–77) |
| Weight average, lb (range) | 179 (120–262) |
| Indication for electrophysiologic study | |
| Supraventricular tachycardia | 15 |
| Nonsustained ventricular tachycardia | 7 |
| Atrial flutter | 3 |
| Wolff-Parkinson-White syndrome | 5 |
| Syncope | 1 |

**Experimental protocol.** Patients who had given informed consent underwent a complete echocardiogram prior to catheter navigation. Monitored conscious sedation was established and maintained with intravenous fentanyl and midazolam during the procedure. Monitoring instruments were compatible with magnetic fields used in this study. Intravascular sheaths were placed in the right and left femoral veins. The magnetic catheter was introduced into the femoral venous access sheath and manually advanced to the region of the RA. Navigation was performed sequentially to each predefined target: high RA, His bundle, lateral tricuspid valve annulus, posterior tricuspid valve annulus, His bundle, and the right ventricular apex. In addition to predefined targets, five additional navigation targets were selected by the operator at the time of the procedure. Navigation success was judged by analysis of intracardiac electrograms and biplanar fluoroscopic views. Stimulation thresholds were also measured at the high RA and the RV apex. At the conclusion of the magnetic catheter navigation, a second echocardiogram was performed. The patient then underwent the scheduled diagnostic electrophysiology study with standard catheters. In a subset of five patients, this included use of a standard 4-mm-tipped deflectable ablation catheter for navigating, recording, and mapping at the same sites as the magnetic catheter.

**Electrogram recording and pacing.** All procedures were performed with a standard multichannel amplifier (Prucka Engineering Inc., Houston, Texas). Intracardiac electrograms were filtered with a bandpass of 30 to 400 Hz and digitized via an analog-to-digital converter at a rate of 1,000 samples/s. Surface electrocardiograms (ECGs) were filtered with a bandpass of 0.05 to 120 Hz prior to digitization at the same sampling rate. Stimulation was performed with a standard, isolated multichannel stimulator (Bloom Inc.). All electrograms were stored optically for analysis. Electrogram analysis was performed with the software package provided with the recording system (Prucka Engineering Inc.).

**Statistical analysis.** A Student *t* test was used for comparison of pacing thresholds, electrogram amplitude, and radiation exposure between the magnetic catheter and the conventional catheter.

## RESULTS

**Electrogram recordings.** Surface ECGs and intracardiac electrograms recorded with both a magnetic catheter and a

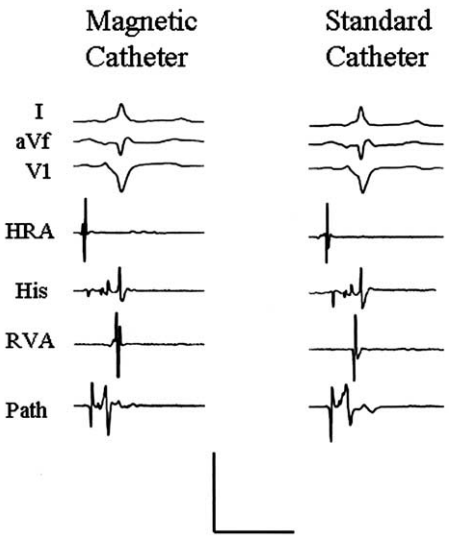


**Figure 3.** Electrogram recordings with a magnetic catheter. Surface electrocardiograms (ECGs) and intracardiac electrograms recorded from a single patient with Wolff-Parkinson-White syndrome are shown. Intracardiac recordings made with both a standard 4-mm-tipped ablation catheter and the magnetic catheter at the high right atrium (HRA), right ventricle apex (RVA), His bundle (His), and ventricular insertion of the accessory pathway are shown. Electrograms were recorded sequentially from the recording sites and are displayed in registry with the surface ECGs. Surface and intracardiac electrograms were not compromised by the magnetic field. The vertical scale is 5 mV, and the horizontal scale is 400 ms.

standard 4-mm-tipped ablation catheter from a single patient with Wolff-Parkinson-White syndrome are shown in Figure 3. Intracardiac electrograms recorded with the MGS were qualitatively unaffected by the presence of the magnetic field. Both catheters recorded similar electrograms at the site of the ventricular insertion of the accessory pathway located on the lateral tricuspid valve annulus. All electrogram recordings were judged to be acceptable by a blinded electrophysiologist.

**Navigation success in the RA and RV.** Catheter navigation was successful to 213 of 215 attempted sites. Table 2 summarizes the results of navigation to all intracardiac targets and the navigation success rate at each site. The catheter failed to reach the RV apex in two patients. In one of these, chamber dilation prevented both the conventional and magnetic catheters from reaching the navigation target in the RV apex. The magnetic catheter design was modified

**Table 2.** Magnetic Guidance System Navigation Success

| Navigation Target | Success/Attempt |
|---|---|
| High right atrium | 20/20 |
| His bundle | 20/20 |
| Posterior tricuspid valve annulus | 20/20 |
| Lateral tricuspid valve annulus | 20/20 |
| Right ventricular apex | 18/20 |
| Right ventricular free wall | 10/10 |
| Right ventricular outflow tract | 6/6 |
| Right ventricular septum | 11/11 |
| Other tricuspid valve annulus sites | 75/75 |
| Left atrium | 13/13 |

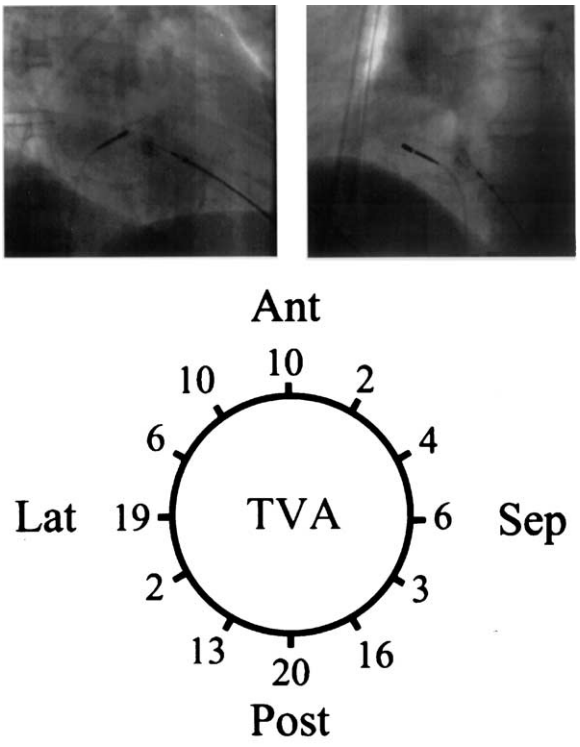


**Figure 4.** Tricuspid annulus recording sites. The distribution of recording sites located around the tricuspid valve are shown schematically. Each recording site was targeted in the left anterior oblique fluoroscopic projection. Recording sites were categorized by the analogous hour position on a clock face. All navigation attempts to sites around the tricuspid annulus were successful. An example of a recording site at the lateral (Lat) aspect (9:00) on the tricuspid valve annulus (TVA) is shown in right anterior oblique **(left)** and left anterior oblique **(right)** images. The septal (Sep), anterior (Ant), and posterior (Post) tricuspid annulus are indicated for orientation.

after the first 20 patients to minimize the catheter transition point that appeared to limit extension of the catheter to the ventricular apex. This problem was not observed in subsequent studies. Figure 4 shows the distribution of sites mapped on the tricuspid annulus. Navigation to all sites around the tricuspid valve annulus was successful.

**Stimulation thresholds.** Pacing thresholds were measured with the magnetic catheter at the high RA and RV apex in all 20 patients. The stimulation thresholds at these sites were in the expected range for a 4-mm-tip mapping catheter. Stimulation thresholds were 1.3 mA (range 0.1 to 2.4 mA, 2 ms pulse width) in the RA and 1.0 mA (0.2 to 2.0 mA, 2 ms pulse width) in the RV apex.

**Equivalence with a standard catheter.** In a subset of five patients, intracardiac electrograms and stimulation thresholds were recorded at the high RA and RV apex with both the magnetic catheter and a standard 4-mm-tipped ablation catheter. Electrogram amplitudes and stimulation thresholds were not significantly different between the two catheters. The average (range) electrogram amplitude recorded in the RA with the magnetic catheter was 2.2 mV (0.8 to 5.9 mV) compared to 1.9 mV (1.1 to 2.8 mV) recorded with the standard catheter. The average (range) electrogram

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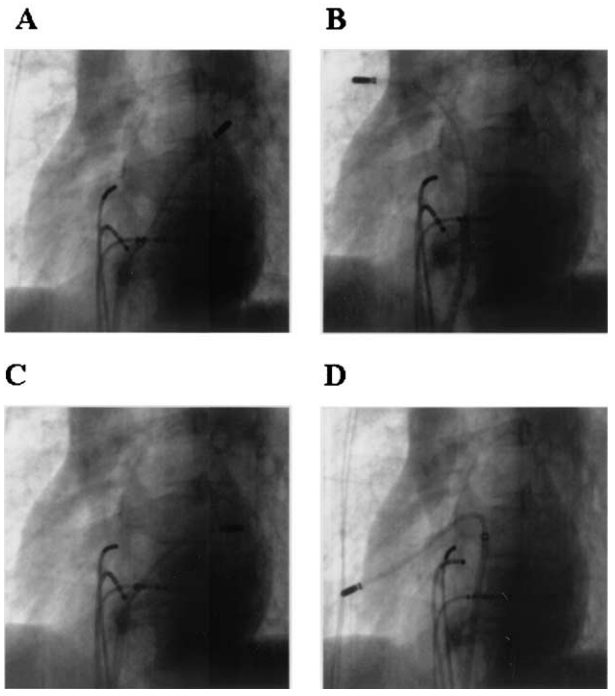


**Figure 5.** Pulmonary vein mapping with a magnetic catheter. The magnetic catheter was introduced into the left atrium through a trans-septal sheath for left atrial mapping in a patient with a left posterolateral accessory pathway. Navigation of the magnetic catheter to each pulmonary vein is shown in left anterior oblique images: **(A)** left superior pulmonary vein; **(B)** right superior pulmonary vein; **(C)** left inferior pulmonary vein; **(D)** the right inferior pulmonary vein.

amplitude recorded in the RV apex with the magnetic catheter was 2.2 mV (0.8 to 5.9 mV) compared to 2.8 mV (1.7 to 5.4 mV) recorded with the standard catheter. The average (range) stimulation threshold recorded in the RA with the magnetic catheter was 1.3 mA (0.1 to 2.4 mA) compared to 1.2 mA (1.0 to 1.5 mA) recorded with the standard catheter. The average (range) stimulation threshold recorded in the RV apex with the magnetic catheter was 1.0 mA (0.2 to 2.0 mA) compared to 0.6 mA (0.2 to 0.8 mA) recorded with the standard catheter.

**Mapping and ablation of SVT.** Intracardiac recordings were made with the magnetic catheter in 13 patients with SVT. Manifest accessory pathways were present in five patients. One pathway was located on the lateral aspect of the tricuspid annulus, and four were located around the mitral valve annulus. In addition, there were seven patients with atrioventricular (AV) nodal re-entry, and one with atrial flutter. In three patients with left lateral accessory pathways, the magnetic catheter was introduced into the left atrium through a trans-septal sheath, and in the other a retrograde aortic approach was used. Figure 5 demonstrates navigation of the magnetic catheter to recording sites within each pulmonary vein in that patient. Figure 6 is an example of recordings, in the same patient, made with the magnetic catheter positioned at the site of a left posterolateral accessory pathway during sinus rhythm and during orthodromic AV re-entrant tachycardia. Intracardiac recordings obtained at the sites of all five accessory pathways were qualitatively equivalent to those obtained with a conventional catheter. The magnetic catheter was also successfully directed to left paraseptal, mid-posterior, and lateral sites along the mitral annulus as defined by the electrodes of the decapolar coronary sinus catheter. In each of the 13 patients who underwent mapping of SVT, the magnetic catheter was guided to a stable position within the reentrant circuit of the arrhythmias, and satisfactory electrograms were recorded. In seven of seven patients with SVT, the magnetic catheter was used for successful ablation of the arrhythmia mechanism (five patients with AV nodal re-entry, two patients with accessory pathways). No complications occurred from the ablation procedures.

**Safety.** There were no cardiac structural abnormalities noted on echocardiograms due to magnetic catheter navigation. In addition, no serious adverse events occurred. One patient developed nausea during the procedure, which was self-limited and did not necessitate termination of the procedure. There were no cases of vascular injury. Phone interviews performed seven to ten days after the procedure did not detect any adverse sequalae of the procedure.

**Fluoroscopic exposure during mapping.** In the subset of five patients in whom the magnetic catheter and a standard catheter were compared, total fluoroscopy times required by three different investigators for intracardiac navigation to ten endocardial sites and pacing at two sites (RA and RV apex) were compared. The total fluoroscopy times in minutes (average ± SD) were for the magnetic catheter 4:24 ± 2:14 and for the standard catheter 5:19 ± 1:23. Although there was a trend for a reduced fluoroscopic exposure with the magnetic catheter navigation, this did not reach statistical significance ($p = 0.43$).

## DISCUSSION

This study is the first human trial of a magnetically guided catheter for intracardiac mapping and ablation of SVT. Our results demonstrate that magnetic force can be used to precisely navigate an electrophysiology catheter within all four chambers of the heart in humans for intracardiac mapping, stimulation, and radiofrequency ablation. Intracardiac electrograms and stimulation thresholds were not significantly different from those recorded with a standard, manually deflected ablation catheter. In addition, the magnetic catheter was used to perform accurate intracardiac mapping and recording in patients with supraventricular arrhythmias. The results of this trial suggest that the safety of standard electrophysiological procedures in not compromised by the MGS.

The MGS is an evolving technology. The initial prototype magnetic catheter failed to reach the right ventricular apex in two patients. The failure appeared to be due to the abrupt transition in catheter stiffness between the proximal shaft and the distal segment. At this site, the proximal

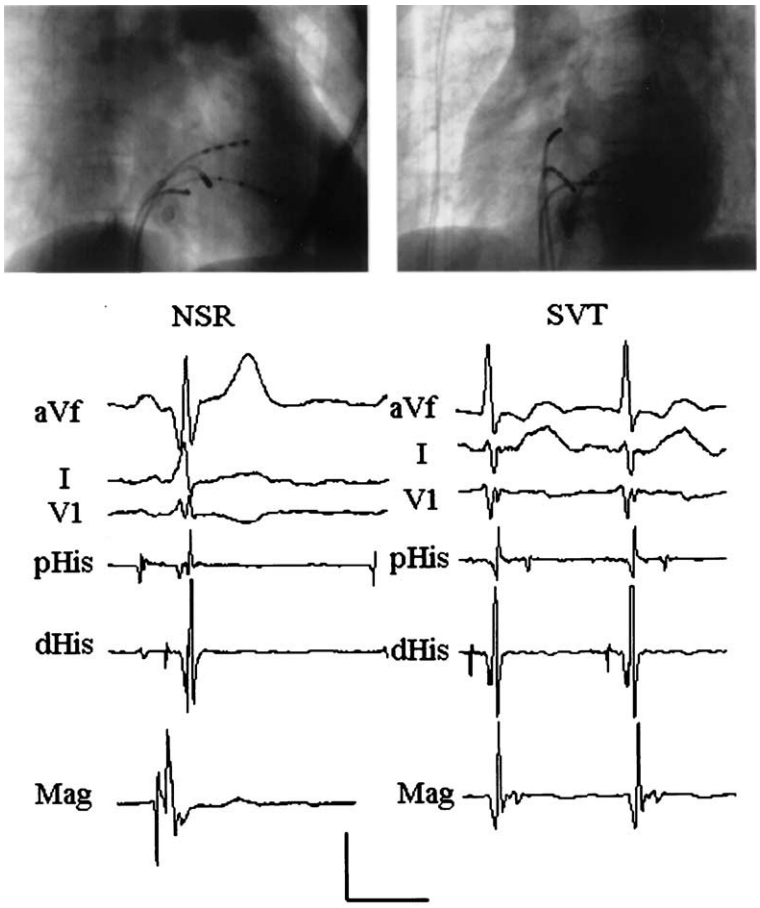


**Figure 6.** Magnetic catheter recordings in a patient with Wolff-Parkinson-White syndrome. The magnetic catheter was introduced into the left atrium by a trans-septal sheath and directed onto the site of a left posterolateral accessory pathway. The right anterior oblique **(left)** and left anterior oblique **(right)** projections are shown of the magnetic catheter positioned at the accessory pathway recording site. Catheters are also shown recording from the right ventricular apex, the His bundle recording site, and within the coronary sinus. Electrogram recordings were made with the magnetic catheter at the accessory pathway site during sinus rhythm and during orthodromic atrioventricular re-entrant tachycardia. Concurrent proximal His (pHis) and distal His (dHis) readings are shown. The vertical scale is 3 mV, and the vertical scale is 400 ms. NSR = normal sinus rhythm; SVT = supraventricular tachycardia.

segment of the catheter prolapsed behind the tricuspid annulus when it was advanced toward the right ventricle. This problem was not observed with the subsequent catheter design, which reduced the transition point to the distal segment. Validation of the new catheter design was performed in experimental animals (4) and humans for the final six patients reported in the present study.

A potential limitation of the MGS is the interference induced by the magnetic field in the surface ECGs. A similar interference has been described with electrocardiography in association with magnetic resonance imaging (5). The origin of the induced potential is thought to be attributable to blood flow within the magnetic field. Blood is an electrolyte solution that may induce the potential owing to motion within the magnetic field. The magnitude of this interference was minimal in the inferior leads of the ECG, and the temporal distribution of the interfering signal component probably would not compromise cardiac rhythm analysis, analysis of P-wave, or QRS morphology. However, interpretation of changes in the ST-segment would be predictably compromised by this interference.

The MGS offers potential advantages over standard catheter systems. Remote control of the MGS is possible from a workstation that would facilitate simultaneous catheter navigation and electrogram analysis, and would eliminate radiation exposure to the physician. In addition, catheter mobility and endocardial stability may be superior by virtue of the compliance of the distal catheter and a lack of constraints on the magnetic vector used to steer the catheter. Cardiac and respiratory motion may be buffered by the catheter compliance, thereby contributing to endocardial contact stability. A unique feature of the current MGS, which is a subsequent modification of the system used for the present trial, is that the magnetic vector coordinates used to navigate the magnetic catheter to a particular site can be stored and reused later in the study to return to a site of interest. The compliance of the catheter and lack of directional constraints on the magnetic vector differ from standard, manually deflected catheters; however, further study is needed to determine whether the MGS is superior to a conventional catheter. The next generation of the MGS is designed to improve speed and accuracy of navigation to

sites that are exceptionally difficult to reach with a standard catheter.

**Study limitations.** A principal limitation in this study was the restriction of navigation targets to the RA and RV in the first 20 patients, which was imposed to protect patient safety for initial tests of the MGS. Most of the targeted endocardial sites are readily reached with a standard, manually deflected catheter. Exceptions may be the lateral and anterolateral tricuspid valve annulus and pulmonary vein ostia where catheter stability can be problematic. At these sites, the MGS appeared to perform well. The current MGS does not offer a distinct advantage over conventional catheters for navigation to targets that are easily reached. Based on our experience in animal studies and the limited experience in humans, the investigators believe the MGS has potential advantages for complex catheter maneuvers, but the current study was not designed to prove this point.

Patients with claustrophobia, obesity, or pacemakers and defibrillators were excluded from the trial because of the restricted space within the MGS or electromagnetic interference, respectively. The next generation of the MGS features an open design that is more comfortable for patients with claustrophobia or morbid obesity. Further study is required to determine whether the magnetic field strength is compatible with pacemakers or internal cardioverter-defibrillators. The magnetic field strength used for catheter manipulation is about one order of magnitude less than that associated with magnetic resonance imaging. The interaction of the magnetic field with the surface ECG is, therefore, less in magnitude to magnetic resonance imaging, and restricted to the ST-segment. Whether this distortion will affect arrhythmia analysis will be investigated in the ongoing SVT ablation trial.

This study represents our initial experience with the MGS in humans and the transition from the first to second magnetic catheter designs. Our use of the system was constrained by caution and protocol stipulations. The trial was not designed to prove the superiority of the MGS over conventional steering mechanisms and should not be construed in that context.

**Conclusions.** This study confirms the feasibility of deploying a novel magnetically guided catheter for electrophysiology studies and ablation of arrhythmias in humans. The MGS directed the catheter to specific targets in the RA, RV, and left atrium safely and effectively.

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